



VETERINARY SERVICES MEMORANDUM NO. 594.2

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Washington, DC
20250

Subject: Export of Animal By-Products to the European Union (EU)

To: VS Management Team
Area Veterinarians in Charge, VS
State Veterinarians

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I. PURPOSE

The purpose of this memorandum is to:

- Explain the general concepts of Regulation (EC) 1774/2002, its related amendments, and other relevant EU legislation covering the export to the EU of animal by-products not for human consumption.
- Standardize Animal and Plant Health Inspection Service (APHIS) field inspections of facilities manufacturing and exporting these products.
- Standardize APHIS procedures regarding certification of these products.



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II. CANCELLATION

This memorandum cancels Veterinary Services (VS) Memorandum No. 594.2, dated January 18, 2000.

III. BACKGROUND

As of May 1, 2004, the following 25 member countries compose the EU: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Sweden, Slovakia, Slovenia, Spain, and the United Kingdom. The EU has established harmonized requirements for the import of many animal by-products into member countries. Each member country may have additional requirements for some commodities, which may be more stringent than the harmonized requirements. In some cases, member countries offer certain derogations or waivers to import requirements.

The EU defines animal by-products as entire bodies or parts of animals, or those products of animal origin included in Category 1, Category 2, or Category 3 materials, that are not intended for human consumption, including ova, embryos, and semen. See section IV, "Definitions," for items that make up the different categories of materials. By-products may include aquatic origin materials such as brine shrimp. This memorandum does not cover the export of ova, embryos, or semen.

Regulation (EC) No. 1774/2002 and its related amendments establish the requirements for importing animal by-products not intended for human consumption into the EU. The regulation does cover animal by-products intended for animal consumption or technical uses (e.g., industrial or pharmaceutical purposes). This regulation does not cover materials to be used as human food. **This regulation also covers the importation of some raw materials that may be incorporated into products such as pharmaceuticals for human consumption.**

The EU classifies materials used for "technical" purposes as "not for human consumption" even though some of these materials may ultimately be consumed by people. These exceptions (e.g., raw materials for pharmaceutical products) are specifically mentioned in this memorandum. Except for these exceptions, this memorandum does not apply to the export of any materials destined for human consumption.

The EU has amended this regulation several times and will likely continue to amend it. These amendments have included additional import requirements and derogations to some requirements. A derogation is a waiver from meeting certain requirements, generally valid for a limited time. Generally, a derogation is specific to a certain product processed in one or more specific countries.

The former EU categorization of by-products into "high-risk" and "low-risk" categories has been replaced by a categorization of by-products into numbered categories: 1, 2, and 3. Previously, some EU countries would accept specified risk materials (SRMs). Now, all SRMs must be removed from most raw materials meant for animal consumption. SRMs are those materials that the EU has deemed highly likely to transmit transmissible spongiform encephalopathies (TSEs). Different countries within and outside the EU may have slightly different definitions of what tissues are considered SRMs.

While the former regulations allowed the handling of "prohibited" material in approved facilities (as long as the material was kept totally separate from prohibited by-products—Categories 1 and 2 materials—from the time it arrived at the processing facility until the time it reached the EU), the new regulations forbid certain facilities from handling any Category 1 or 2 materials. Facilities not allowed to handle any Category 1 or 2 materials include facilities handling the following materials:

1. Processed animal protein (e.g., rendered meals).
2. Blood products that could be used as feed (e.g., spray dried blood).
3. Rendered fats.
4. Hydrolyzed protein.
5. Dicalcium phosphate.
6. Tricalcium phosphate.
7. Inedible egg products.

Effective only through October 31, 2005, the EU has issued a derogation allowing these U.S. facilities to continue to handle all types of materials if adequate measures are taken to ensure complete separation of the eligible Category 3 materials from other ineligible materials at all times.

Other types of facilities remain able to handle ineligible materials as long as those products are kept totally separate from the eligible materials.

Some materials that facilities previously could include in materials produced for export to the EU are now prohibited for most uses. These materials are derived from animals that died in transit and were not presented for ante mortem examination.

With few exceptions (detailed in the definition of Category 3 materials), materials derived from animals that did not pass post mortem inspection are ineligible for inclusion in materials for animal consumption.

The new requirements also call for facilities to meet certain sanitary, structural, and processing standards. Most facilities are also required to have in place quality assurance programs (self-inspection plans) similar to those developed under the Hazard Analysis and Critical Control Points (HACCP) system.

In some cases, the requirements to import by-products into the EU under Regulation (EC) 1774/2002 for purposes such as animal consumption are more stringent than the requirements to import the same material into the EU for human consumption. These requirements are established by the EU, not by the U.S. Department of Agriculture (USDA).

IV. DEFINITIONS

A. Category 1 materials

1.1 All body parts including hides and skins of the following animals:

- Animals suspected or confirmed of being infected with a TSE, or killed as part of a TSE eradication measure;
- Pet animals, zoo animals, and circus animals;
- Experimental animals (defined in 86/609/EEC); and
- Wild animals infected with a zoonotic disease.

1.2 **SRMs.** In this memorandum, SRMs are those materials that the EU has deemed highly likely to transmit TSEs. The EU definition of SRMs is different from the U.S. definition. The EU considers SRMs to include:

- The skull (excluding the mandible and including the brain and eyes), the vertebral column (excluding the vertebrae of the tail, the transverse processes of the lumbar, thoracic vertebrae, and the wings of the sacrum, but including dorsal root ganglia), and the spinal cord of bovine animals aged over 12 months; and the tonsils, the intestines from the duodenum to the rectum, and the mesentery of bovine animals of all ages.
- The skull including the brain and eyes, the tonsils, and the spinal cord of ovine and caprine animals aged over 12 months or that have a permanent incisor erupted through the gum; and the spleen and ileum of ovine and caprine animals of all ages.
- Entire carcasses if the above materials are not removed.
- Mechanically recovered meat produced after March 31, 2001, from the bones of cows, sheep, or goats.

- Animals that were slaughtered by means of gas injection into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of the central nervous system by means of an elongated rod-shaped instrument introduced into the cranial cavity.**

**After consulting with the Food Safety and Inspection Service (FSIS), APHIS has determined that the captive bolt is used in most plants. There are two types of captive bolts: one using a cartridge similar to a bullet to drive the bolt into the brain and the other using air (pneumatic captive bolt) to drive the bolt into the brain (air is not injected into the cranial cavity). Both of these methods are acceptable and do not fall under the banned methods described above.

Some EU member countries (e.g., France) may have more extensive SRM definitions. Where APHIS is aware of these expanded SRM requirements, the requirements will be posted under the pertinent member country on the International Animal Product Export Regulations (IREGs). Approval by APHIS of a facility as meeting the requirements of Regulation (EC) 1774/2002 does not mean that the facility meets the requirements to export to all EU member countries.

- 1.3 Products derived from animals administered substances prohibited under the EU Council Directive 96/22/EC of April 29, 1996. **(These materials, although technically Category 1, may be included in pet food and pet food precursors exported to the EU for the production of pet food.)** These prohibited products include any substances having a thyrostatic, oestrogenic, androgenic, or gestational action, and beta-agonists, with the following exceptions:

- Oestradiol 17 a, testosterone, progesterone, and derivatives that readily yield the parent compound after absorption at the site of application, administered for therapeutic purposes to farm animals, under veterinarian supervision, and not by implant.
- Allyl trenbolone, administered orally, or beta-agonists to equidae and pets.
- Beta-agonists, administered injectably, to induce tocolysis in cows.
- For the purpose of zootechnical treatment (reproduction), veterinary medicinal products having oestrogenic, androgenic, or gestagenic action.

1.4 Products containing residues exceeding permitted levels (levels laid down by community legislation or, in the absence thereof, by national legislation) of substances prohibited under Group B (3) of Annex I to Council Directive 96/23/EC. These substances include:

- Organochlorine compounds including PCBs.
- Organophosphorus compounds.
- Chemical elements.
- Mycotoxins.
- Dyes.
- Others, including unlicensed substances that could be used for veterinary purposes.

1.5 Catering waste from international transport.

1.6 Category 2 or Category 3 materials mixed with Category 1 materials.

1.7 All animal material collected from the treatment of wastewater from Category 1 processing plants or SRM removal plants.

B. Category 2 materials

2.1 Manure and digestive tract contents of mammals and ratites.

2.2 All animal materials collected from the treatment of waste water from slaughterhouses handling Category 2 or Category 3 materials.

2.3 Products of animal origin containing residues of veterinary drugs and contaminants listed in Group B (1) and (2) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level established by community legislation.

Group B of Annex I to Directive 96/23/EC – Veterinary drugs and contaminants:

- Antibacterial substances, including sulphonamides, quinolones;
- Other veterinary drugs;
- Anthelmintics;
- Anticoccidials, including nitroimidazoles;
- Carbamates and pyrethroids;
- Sedatives;
- Nonsteroidal anti-inflammatory drugs; and
- Other pharmacologically active substances.

2.4 Products of animal origin other than Category 1 material imported from nonmember States that fail import restrictions.

2.5 Animals and parts of animals that die other than by slaughter for human consumption.

2.6 Mixtures of Category 2 material with Category 3 material.

2.7 Animal by-products not included under Category 1 or Category 3 materials.

C. Category 3 materials

These are the materials that, in general, may be included in animal feed: animal by-products of the following descriptions, or any material containing such by-products.

3.1 Parts of slaughtered animals that are fit for human consumption.

3.2 Parts of slaughtered animals that are rejected as unfit for human consumption, but are not affected by any signs of diseases communicable to humans or animals, and are derived from carcasses that are fit for human consumption.

3.3 Hides and skins, hooves and horns, pig bristles, and feathers from animals that passed ante mortem inspection.

3.4 Blood from nonruminants that passed ante mortem inspection.

3.5 Animal by-products derived from the production of products fit for human consumption, including degreased bones and greaves.

3.6 Former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste, that are no longer intended for human consumption for commercial reasons and that do not present any risk to humans or animals.

3.7 Raw milk originating from animals that do not show clinical signs of any disease communicable through that product to humans or animals.

3.8 Fish or other sea animals, except sea mammals, caught in the open sea for purposes of fishmeal production.

- 3.9 Fresh by-products from fish from plants manufacturing fish products for human consumption.
 - 3.10 Shells, hatchery by-products, and cracked egg by-products originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals.
 - 3.11 Blood, hides and skins, hooves, feathers, wool, horns, hair and fur originating from animals that did not show clinical signs of any disease communicable through that product to humans or animals.
 - 3.12 Poultry heads, feet, and intestines from slaughter facilities. These specific materials do not need to have been from birds passed for human consumption.
- D. **Animal:** In this memorandum, this term will apply to any vertebrate or invertebrate animal including fish, reptiles, and amphibians but not including insects.
 - E. **Animal by-products:** In this memorandum, this term will apply to entire bodies or parts of animals, or those products of animal origin in Category 1, Category 2, or Category 3 materials, not intended for human consumption, including ova, embryos, and semen.
 - F. **Approved facility:** In this memorandum, this term will apply to facilities approved by APHIS either to export animal by-products directly to the EU or to supply animal by-products to facilities that are approved to export directly to the EU.
 - G. **Catering waste:** In this memorandum, this term will apply to all waste food including used cooking oil originating in restaurants, catering facilities, and kitchens and household kitchens.
 - H. **Collagen:** In this memorandum, this term will apply to protein-based products (not processed to the point of becoming gelatin) derived from hides, skins and tendons of animals, including bones in the case of pigs, poultry, and fish.
 - I. **Edible:** In this memorandum, this term will apply to those materials approved for human consumption by a competent government authority in the United States.

Note: Those materials that the USDA deems to be edible may be exported to another country as inedible. For example, the USDA may consider a lot of tallow to be edible (or fit for human consumption), but the exporter may choose to export the material (if it meets all necessary requirements) to an EU member country for technical purposes, such as raw materials for the production of industrial lubricants. The material, considered to be edible by the USDA, would, in this case, actually be exported for purposes other than human consumption.

- J. **Gelatin:** In this memorandum, this term will apply to inedible natural, soluble protein, gelling or nongelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons, and sinews of animals (including fish and poultry).
- K. **Harmonized import certificate:** In this memorandum, this term will apply to the standard zoosanitary certificate that the EU has published to be used to import a given commodity into a member country from outside the EU.
- L. **Hydrolyzed protein:** In this memorandum, this term will apply to polypeptides, peptides, and amino acids, and mixtures thereof, obtained from the hydrolysis of animal by-products.
- M. **Inedible:** In this memorandum, this term will apply to those materials that are not approved for human consumption by a competent government authority in the United States.
- N. **Last Validated Inspection Date:** In this memorandum, this term will apply to the last date the facility was inspected, for which the inspection checklist and associated forms have been confirmed, through the entire APHIS review process, to indicate the facility should be approved.
- O. **Oleochemical:** In this memorandum, this term will apply to material derived from fat through transesterification, hydrolysis, or saponification. Examples include glycerol, fatty acids, and esters.
- P. **Pre-inspection package:** In this memorandum, this term will apply to a document created by the National Center for Import and Export (NCIE) to assist the area office and in preparing for and conducting the facility inspection. The document is also designed to assist the facility management in completion of the necessary pre-inspection steps and in preparation for the inspection.

V. TYPES OF APPROVED FACILITIES

The following types of facilities require APHIS approval under Regulation (EC) 1774/2002 if they wish to export to the EU or supply other facilities that are exporting to the EU.

- A. **Category 2 rendering facility:** A facility producing fat products for oleochemical production through the high temperature and/or high pressure treatment of Category 2 materials. Products include items such as tallow and lard.
- B. **Category 3 rendering facility:** A facility producing meals or fats through the high temperature and/or high pressure treatment of Category 3 materials. Products include items such as meat-and-bone meal, tallow, and lard.
- C. **Game trophy facility:** A facility processing or exporting game trophies of ungulates or birds for export to the EU. (This does not include facilities exporting trophies that have received a complete taxidermy treatment to ensure their preservation at ambient temperatures.)
- D. **Dairy facility:** A facility producing a product not for human consumption where the product does contain dairy ingredients, but does not contain any other items derived from animals.
- E. **Dicalcium phosphate facility:** A facility approved to produce dicalcium phosphate from Category 3 bones for export to the EU.
- F. **Digest/flavoring innard production facility:** A facility that produces a liquid or dehydrated flavoring that is used to enhance the palatability values of pet food. (The EU refers to this product as a flavoring innard.)
- G. **Fresh hides or skins facility:** A facility exporting untreated hides or skins of ungulates to the EU.
- H. **Hydrolyzed protein facility:** A facility approved to produce hydrolyzed protein from Category 3 materials for export to the EU for purposes other than animal feeding.
- I. **Inedible blood (for animal feeding facility):** A facility that is not under the inspection of FSIS that produces an inedible blood product from Category 3 materials through a heat treatment other than rendering.

- J. **Inedible collagen facility:** A facility processing Category 3 material into collagen not meant for human consumption for export to the EU or for inclusion in products exported to the EU.
- K. **Inedible egg facility:** A facility that produces an inedible egg product from Category 3 materials through a heat treatment other than rendering.
- L. **Inedible gelatin facility:** A facility processing Category 3 material into gelatin not meant for human consumption for export to the EU or for inclusion in products exported to the EU. (Does not include photo gelatin, which has separate package.)
- M. **Laboratory facility:** A facility approved by APHIS to conduct microbial tests on materials from facilities approved to export to the EU.
- N. **Oleochemical facility:** A facility producing an oleochemical from Category 2 or 3 fats for export to the EU. This does not apply to facilities exporting finished products such as paints and soaps containing oleochemicals such as fatty acids or esters.
- O. **Pet food manufacturer:**
 - 1. A facility producing finished materials (containing animal origin ingredients other than only dairy) for the consumption of pets; or
 - 2. A facility producing any commodity that the importing EU member country requires to be imported on any of the following Regulation (EC) 1774/2002 health certificates:
 - a. Chapter 3(A) health certificate for canned pet food intended for dispatch to the European Community (EC);
 - b. Chapter 3(B) health certificate for pet food other than canned pet food, intended for dispatch to the EC;
 - c. Chapter 3(C) health certificate for dog chews intended for dispatch to the EC; or

3. Any facility where the required heat treatment is conducted on any animal origin pet food ingredient, if the final pet food is not heated to 90 °C at the final pet food production facility. [The EU requires pet food other than canned pet food or dog chews (made from ungulate skin) to be heated to 90 °C under certain requirements. An example of pet food other than canned includes kibble. Pet food facilities that cannot heat the final pet food product in its entirety under these conditions may be approved if each animal origin component was heated to 90 °C at a facility approved as a pet food facility, thus requiring some suppliers to be approved as pet food facilities.]
- P. **Photographic gelatin facility:** A facility that produces photographic gelatin for export to the EU.
- Q. **Photographic gel bone facility:** A rendering facility approved to produce rendered bone chips to supply gel bone to certain facilities in the United States producing gelatin for photographic purposes.
- R. **Processed manure facility:** A facility that processes manure (including poultry litter) of livestock or birds for export to the EU for use as fertilizer.
- S. **"Raw Animal By-Products for Fur-Animal Feeding" Facility:** A facility that is exporting finished "Raw Animal By-Products for Fur-Animal Feeding" made from animal parts from animals whose carcasses have been found fit for human consumption, or fish that is fit for human consumption. This package is only for these facilities exporting materials on the "*Chapter 3(D) Health Certificate for Raw Pet Food for Direct Sale or Animal By-Products to be fed to Farmed Fur Animals, Intended for Dispatch to the European Community.*"
- T. **Raw Pet Food Facility:** A facility that is exporting finished raw pet food made from only the parts of animals or fish that are fit for human consumption.
- This package is only for these facilities exporting materials on the "*Chapter 3(D) Health Certificate for Raw Pet Foods for Direct Sale or Animal By-Products to be fed to Farmed Fur Animals, Intended for Dispatch to the European Community.*"
- U. **Supplier of unprocessed animal by-products for pet food production:** A facility exporting Category 3 materials (other than those specifically covered by another facility type) directly to the EU for production of pet food, or an intermediate supplier of these materials to U.S. producers of pet food to be exported to the EU.

- V. **Supplier of unprocessed animal by-products for production of technical products including pharmaceuticals:** A facility exporting Category 3 materials (other than those specifically covered by another facility type) directly to the EU for production of technical products other than for animal feeding. Materials used for production of pharmaceuticals for human consumption may be required to come from these facilities. Exporters should have their importers confirm with the Ministry of Agriculture in the importing member country that the Regulation (EC) 1774/2002 Chapter 8(B) certificate is the appropriate certificate to import the material prior to seeking this approval.
- W. **Technical blood facility (equidae):** A facility approved by APHIS to collect, process, or export blood and blood products derived from equidae animals to be used for technical purposes (other than animal feeding), including pharmaceuticals, in vitro diagnosis, and laboratory agents to the EU APHIS-Animal Care registration is not equivalent to the APHIS Regulation (EC) 1774/2002 approval.
- X. **Technical blood facility (non-equidae):** A facility approved by APHIS to collect, process, or export blood and blood products derived from livestock and poultry (other than equidae animals) to be used for technical purposes (other than animal feeding), including pharmaceuticals, in vitro diagnosis, and laboratory agents to the EU. APHIS-Animal Care registration is not equivalent to the APHIS Regulation (EC) 1774/2002 approval.
- Y. **Third party facility:** A facility that exports materials finished at another facility approved by APHIS to export that material to the EU. The material must not be commingled with any other animal origin material after leaving the APHIS approved processing facility. This facility must be in the United States.
- Z. **Treated hides and skins facility:** A facility, including FSIS and State inspected slaughter facilities, processing hides or skins of ungulates for export to the EU. (This does not include facilities exporting finished leather to the EU. This does not include facilities exporting dog chews made from the skins of ungulates to the EU, or facilities exporting hides for the production of dog chews in the EU.)
- AA. **Tricalcium phosphate facility:** A facility approved to produce tricalcium phosphate from Category 3 bones for export to the EU.

- BB. Unprocessed wool, hairs, pig bristles, feathers, and parts of feather facility:** A facility that exports unprocessed wool, hairs from ungulates, pig bristles, feathers, or part of feathers to the EU.

VI. PRE-INSPECTION PROCEDURES

A. Pre-inspection packages

Pre-inspection packages are documents created by the NCIE to assist the area office in preparing for and conducting the facility inspection. The packages are also designed to assist the facility management in completion of the necessary pre-inspection steps and in preparation for the inspection. The packages do not necessarily contain guidance on all information that may be required from the facility and the inspection, as each facility could vary significantly in its structure, processes, and suppliers.

The current pre-inspection packages are available to area offices on the Information Dissemination Electronic Access (IDEA) system, which is available on APHIS computers at:

<http://inside.aphis.usda.gov/property/apps/idea.html>. The pre-inspection packages are available through the selection entitled "Documents Regarding Approvals for the Export of Animal By-Products to the European Union." Whenever a package is updated, NCIE will post the current version on the IDEA System. Before forwarding a package to a facility or conducting an inspection, area offices must ensure that they have the current version of the package.

B. Forwarding pre-inspection packages

Before scheduling the inspection, the area office should forward the appropriate pre-inspection package to the facility. When the area office initially forwards the package to the facility, the area office must advise the facility to:

- Forward the required documentation to the area office for evaluation before the inspection can be scheduled, with a cover letter stating what materials (including species of origin) the plant wishes to be approved to produce and the contact information of the plant contact.
- Have copies of all required documents available for review at the beginning of the inspection.
- Be in production at the time of the inspection.

- Be prepared to demonstrate any required sampling techniques, performing at least one collection of each required sampling at the time of the inspection.
- Have a knowledgeable and responsible individual accompany the inspector during the inspection to explain procedures and address all questions on the inspection checklist.
- Have the laboratory director available for an interview, if the plant uses an in-house laboratory for any required laboratory testing.

At this time, area office personnel must inform the plant management of the applicable hourly rate user fee.

C. Reviewing pre-inspection documentation

In most cases, packages will require facilities to submit certain documentation to the area office before inspection. Pre-inspection review is the responsibility of the area office. **Area offices must confirm that this documentation meets certain requirements before inspection.** This will prevent unnecessary repeat inspections, as well as inspection of facilities that are obviously unable to meet the criteria. The pre-inspection packages detail how to conduct this document review for each facility type. The area office should not forward entire documents to NCIE for review at this stage; details for submitting the inspection package are in section XII, B.

VII. REQUIRED FORMS

Before scheduling the inspection of any facility, area office personnel must confirm that they have current versions of the various required documents that meet all the requirements as described in the relevant pre-inspection package.

"Notarized forms" must be the exact forms included in the appropriate package and must be notarized. The notarized forms must also list the title (or the position held in the company) of the signatory. The title or position must indicate that the individual could be expected to have knowledge of the information included in the notarized form. If attachments are utilized with a notarized form, these attachments must clearly be part of the same notarized document. The body of the document must reference the attachments. Each page of the document must be numbered (Page X of Y). The signatory of the document must initial and date each page.

Only individuals who have received training on Regulation (EC) 1774/2002 may conduct document review. If an individual may be required to conduct document review and has not yet received training on Regulation (EC) 1774/2002, the individual should contact his or her regional import/export coordinator (IEC) for assistance.

Some descriptions of documentation required for most facilities follow:

A. Category 3 Material Notarized Form

This form, where required, is included in the appropriate pre-inspection package.

This form must state that Category 1 and Category 2 materials are kept separate from materials to be exported to the EU and provide specifics on the method of separation. For facilities not allowed to handle Category 1 or 2 materials, this form must state that only Category 3 materials are received, stored, or processed in the building. **If a material does not come from an approved source, it cannot be considered Category 3.**

The notarized form should specify what types (species of origin and form of material; e.g., rendered porcine meat-and-bone meal) of Category 3 materials are handled by the plant and specify the suppliers. The form must also include the approving authority and any applicable approval numbers for each supplier. Section VIII discusses examples of approving authorities other than APHIS.

An exception to this requirement (for an approving authority and number) is ocean-caught fish or other sea animals (except mammals) where no approval number or authority name is required. Rather than approval numbers, a statement should be included that these materials only include fresh caught fish or other sea animals (except mammals).

B. Notarized SRM Form

This form is included in the appropriate pre-inspection package.

This form must state that any SRMs are kept separate from materials to be exported to the EU and provide specifics on the method of separation. For facilities not allowed to handle Category 1 or 2 materials, this form must state that no SRMs are received, stored, or processed in the building. If a material does not come from an approved source, it cannot be considered to be SRM free.

C. Notarized Approved Laboratory Form

This form is included in the appropriate pre-inspection package and must state at what approved laboratory any required laboratory work is performed.

D. Self-inspection program

The EU requires certain facility types to have in place a quality assurance program similar to the HACCP. The pre-inspection package indicates if this is required.

Simply put, the HACCP system requires the facility to examine each type of hazard to which food might be exposed. Examples of hazard categories include: physical (e.g., metal contamination), biological (e.g., bacteria and viruses), and chemical (e.g., residues). The facility identifies whether or not each hazard could be present at its facility, then determines at what point (receiving, cooking, packaging, etc.) the hazard could be introduced, eliminated, or decreased to an acceptable level. This point is defined as the critical control point (CCP).

An example of a CCP is the point during processing when the material reaches the maximum temperature. The facility then determines at what point, and under what conditions, the hazard can be eliminated. The condition required to eliminate the hazard is the critical limit (CL). An example of a CL is a requirement to heat all pet food to 90 °C.

Unlike HACCP, Regulation (EC) 1774/2002 does not permit facilities to use a hazard analysis to justify removal of a given CCP. While the CCPs and CLs in HACCP are based upon hazard analysis, the self-inspection programs required by Regulation (EC) 1774/2002 differ from HACCP in that the CCPs and CLs are dictated by the regulation. HACCP requires a risk assessment; Regulation (EC) 1774/2002 requirements are not based upon risk assessment. Instead, Regulation (EC) 1774/2002 requires a self-inspection program that must meet minimum requirements including meeting specific CCPs/CLs for pet food facilities (and several other types of operations). The pre-inspection package will explain these requirements.

This facility's self-inspection program must have all of the following elements in writing:

- The specific CCPs and CLs as indicated by the pre-inspection package.
- Procedures to follow if a CL is not met: If product is produced without meeting a CL, the plan must state that the area office will be notified that the material is destroyed, reprocessed, or sold domestically.
- A **process flow diagram** demonstrating where each of the CCPs is located in the process. For any required CL, a CCP location must be noted.

E. **Notarized Processing Method Form**

As required, this form is included in the appropriate pre-inspection package and must state that product is processed in a certain way. Often this form will require the plant to certify certain aspects of the self-inspection plan.

F. **Written procedures to prevent commingling or cross-contamination**

Facilities that are allowed to receive, store, or process Category 1 or 2 materials must have written procedures for preventing commingling or cross-contamination with the Category 3 materials used to produce product for export to the EU (if they do receive, store, or process Category 1 or 2 materials). These procedures must be consistent with those described in Appendix One under "How can I provide for measures to avoid commingling or cross-contamination?" These written procedures must clearly identify which materials are eligible for export to the EU, which are not, and ensure that these materials are kept totally separate the entire time they are in the facility.

VIII. REQUIREMENT THAT ALL ANIMAL ORIGIN INGREDIENT SUPPLIERS BE "APPROVED"

The EU requires that U.S. facilities exporting animal by-products be inspected and approved by APHIS prior to export. In addition, all facilities that provide ingredients of animal origin must be inspected and approved. In cases of some ingredients, APHIS is able to accept approval from other government agencies as meeting this requirement.

A. **Fishmeal and fish oil**

Facilities producing fishmeal or fish oil to be used as ingredients in pet food may be approved by either the National Oceanic and Atmospheric Administration (NOAA) or APHIS. If the fishmeal or fish oil producing facilities are not approved by NOAA, but are inspected and approved by APHIS, this approval is only for supplying fishmeal or fish oil to pet food producing facilities in the United States or Canada. APHIS approval does not apply to the exportation of fishmeal or fish oil directly to the EU. **APHIS, VS, personnel may not sign export certificates for fishmeal or fish oil to the EU. These fishmeal and fish oil certificates must be signed by NOAA.** Contact information for NOAA:

Fish Meal Program Manager
National Marine Fisheries Service
National Oceanic and Atmospheric Administration
P.O. Drawer 1207
Pascagoula, MS 39567
Telephone: 228-762-7402, ext. 312
Fax: 228-762-9200

B. Imported animal origin ingredients

If ingredients are imported into the United States, the imported material must be accompanied by an original certificate endorsed by a full-time, salaried veterinary official of the exporting country's national animal health agency, certifying all applicable requirements on the EU import certificate for the final product. This certificate from the government of the country of origin must include all certification statements required to export the material to the EU, or have an acceptable substitute statement, such as "The certified materials meet all requirements for inclusion in [*insert the intended derivative of the ingredient*] for export to the EU under Regulation (EC) 1774/2002 and its related amendments."

The exception is for meals from countries that the EU has classified as BSE risk-category 1 or 2 (for example, Australia or New Zealand). Meals from these countries are not required to have the SRMs removed. Therefore, the government certificate would not need to include certification of SRM removal.

Where alternative certification language has been agreed upon with certain other countries, specific information is available on the Export Animal Product Database in the message entitled "Regulation (EC) 1774/2002 Pre-Inspection Packages."

Certifications that materials meet U.S. import requirement or APHIS import permits are not relevant here because the requirements to export the material to the EU differ from APHIS import requirements.

If a material is imported from a third country and not further processed in the United States, the U.S. exporter must obtain certification from the country of origin that is required by the country that will be importing the materials from the United States. APHIS would then, after confirmation by inspection, attach a VS Form 16-4 stating that the material was not commingled with any other animal origin material while in the United States.

C. FSIS or State approved facilities

FSIS and State approved slaughter facilities may also supply materials that obviously do not contain SRMs. The APHIS approved facility must note, on its "Category 3 Material Notarized Form," which suppliers are FSIS or State approved slaughterhouses and include their official numbers. Facilities supplying materials that may contain SRMs, e.g., rendered ruminant fat (tallow), must be approved by APHIS.

If a material, except for hides and in some cases inedible egg products, is produced entirely under FSIS inspection, then FSIS is the agency responsible for endorsing export certificates for the product to the EU.

D. Dairy facilities

The Food and Drug Administration (FDA) approves dairy facilities to export products to the EU for human consumption. These facilities (approved by FDA to export to the EU) may provide materials to facilities seeking APHIS approval under Regulation (EC) 1774/2002. Listings of these approved facilities may be found on the Agriculture Marketing Service (AMS) Web site. The Web address is http://www.ams.usda.gov/dairy/eu_prgm.htm. Once at this Web address, select "List of Approved European Union Exporters" to reach the list.

APHIS approves facilities producing pet food and other products containing dairy materials for export to the EU not for human consumption. This APHIS approval does not allow facilities to export dairy products directly to the EU, **unless** the product is not for human consumption. This APHIS approval also does not allow facilities to export products containing any animal origin materials other than dairy to the EU.

E. Eggs and egg by-products

Facilities supplying eggs and egg by-products must also be approved. The APHIS approved facility must note, on its "Category 3 Material Notarized Form," the approval number of the supplier. The notarized form should state whether the approval number is issued by APHIS, AMS, FSIS, or a State agency (specify which agency).

F. Other "foodstuffs" fit for human consumption

If ingredients are from grocery stores or other sources in the United States where the products are on sale for human consumption, and obviously do not contain SRMs, the "Category 3 Material Notarized Form" should include a detailed description of the source and processing of the material and under what authority the production is regulated.

IX. INSPECTION PROCEDURES**A. Before the inspection**

1. Only individuals who have received training on Regulation (EC) 1774/2002 can conduct inspections. If an individual may be required to conduct inspections and has not yet received training on Regulation (EC) 1774/2002, the individual should contact the IEC for assistance
2. Before arriving at the plant for the inspection, the inspector must review the documents already sent to the area office and the appropriate pre-inspection package.

B. Beginning the inspection

1. The inspection should begin in the plant management office. The inspector must review the required documents with plant management at this time.
2. Next, the inspector should review the checklist with the plant tour guide to establish that all questions should be addressed during the tour.

C. Inspecting the facility

1. The guide should then accompany the inspector through the facility, addressing each item on the checklist.
2. During the inspection, the inspector must keep in mind the information he or she has reviewed in the supplied notarized forms and diligently observe for any indications of inaccuracies.

3. The inspector must scrutinize the receiving area in the plant. If any intact feathered or haired carcasses are present, there is a high likelihood that the plant is processing "died in transits" or other carcasses that have not received post mortem inspection and therefore are not from Category 3 plants. If the facility does not list a separation protocol on its Category 3 Material Form, the inspector should look carefully for materials from suppliers not listed on the Category 3 Material Form.
4. If the laboratory conducting required tests is located at the facility, the inspector must tour the laboratory facility, meet with the laboratory director, and complete the "US Laboratory Approval Checklist" (available on the Export Animal Products Database). See section X, "Laboratory Approval/Microbiological Testing."
5. Before the end of the inspection, the inspector must select a lot of finished product and ask to see all records for that lot. The facility must produce records showing that:
 - a. The raw materials were supplied from approved suppliers listed on the Category 3 Material Notarized Form (if one is required); and
 - b. All CLs were met (if a self-inspection plan is required for this facility type) for the lot in question.

D. Completing the inspection

At the end of the tour, the inspector should review the checklist and ask the guide to return to any areas necessary or to show the evidence for any unanswered question.

X. LABORATORY APPROVAL/MICROBIOLOGICAL TESTING

A. Approved laboratories

1. If a facility is required to test for salmonella, clostridium, or enterobacteriaceae, an "approved laboratory" must conduct the testing. To be approved, laboratories must be inspected by APHIS. (While other laboratory tests may be required, APHIS is not required to inspect the laboratories doing other tests.)

- a. If the laboratory is located on the facility premises, the area office should conduct the laboratory inspection during the facility inspection. During this inspection, the area office should complete the U.S. Laboratory Inspection Checklist included in the appropriate supplement and forward the checklist to NCIE with the facility inspection package.
 - b. If the laboratory is located off the facility premises, APHIS must inspect the laboratory and complete the U.S. Laboratory Inspection Checklist. APHIS will then evaluate this information and determine whether to approve the laboratory.
2. APHIS will list off-site laboratories approved by APHIS to conduct microbiological tests for approved facilities on the IDEA System, <http://inside.aphis.usda.gov/property/apps/idea.html>, under "Approved Export Facilities under EU Regulation 1774/2002."
 3. VS has determined that any laboratory accredited by the National Environmental Accreditation Program (NELAP) or the American Association of Veterinary Laboratory Diagnosticians (AAVLD) would meet or exceed the criteria for approval by APHIS to conduct work for exporters wishing to be approved by APHIS as meeting the requirements of Regulation (EC) 1774/2002. Therefore, facilities may utilize laboratories approved specifically by APHIS to conduct this testing, or facilities approved by either NELAP or AAVLD.

If a facility is utilizing an NELAP or AAVLD approved laboratory, the pertinent approved laboratory forms and checklists from the pre-inspection packages should note the name of the laboratory and that it is NELAP or AAVLD approved. The facility should provide evidence of this approval to the inspector.

B. Combination of test samples

In 2001, VS decided to permit the combining of test samples for the EU and other countries that require multiple test samples. Research shows that when samples are properly combined, the results can be considered equivalent to performing the tests separately.

When the EU requires five 25-gram samples randomly taken from each batch of animal feed or similar product, the exporter should submit five samples to the laboratory. The laboratory may then weigh out the samples and combine them to make a single 125-gram sample. The laboratory may then test that entire sample.

The laboratory report must indicate that five 25-gram samples were combined to form a composite sample test result. Area veterinarians in charge (AVICs) may verify the protocol with the laboratory personnel if they have questions or concerns.

C. Rapid tests

The use of rapid tests for salmonella and enterobacteriaceae is acceptable provided a validation test is performed at regular intervals (at least annually) at an APHIS approved laboratory using methods other than rapid tests.

XI. BILLING FOR INSPECTIONS

The area office must bill by the hour for inspections to approve facilities and any required followup inspections (Title 9, *Code of Federal Regulations*, Parts 156 and 130).

XII. SUBMITTING AND APPROVING INSPECTION REPORTS

A. Completing the checklist

1. The area office must complete all blanks on the checklist legibly. If the inspector's notes taken during the inspection are illegible, the area office must either type the checklist or complete it again in legible block letters. NCIE will return illegible checklists/forms to the area office for typing.
- b. Once the inspector has conducted the inspection and completed the checklist, the AVIC must review the checklist and required documents and confirm that requirements are met. (The pertinent pre-inspection package contains details on the approval criteria.) The checklist will indicate which forms the area office forwards to NCIE. Once the AVIC confirms the documentation is acceptable, the AVIC must sign the checklist before forwarding the checklist and required forms to NCIE.

- c. If the AVIC chooses to forward to NCIE a package where one or more deficiencies have been noted, but are pending resolutions, the AVIC should attach a cover letter noting that the facility has been advised of these deficiencies and that the approval will not be granted until the area office has confirmed that the deficiencies have been resolved.

B. Submitting the inspection package

1. The area office submits a copy of the *completed* inspection checklist (from the relevant current pre-inspection package) and all required notarized forms to NCIE, Attention: Products Export Team, fax 301-734-0571. The area office may also send the documents by courier directly to NCIE to the address indicated on the Export Animal Products Database in the document entitled "Proper Fed Ex Address, Email Address, Phone, and Fax Number to Reach the Animal Products Export Team."
2. The area office must maintain a copy of the inspection package and all forms.

C. Approving the facility

1. If NCIE determines that additional information is required to approve the facility, NCIE will request from the area office followup information that may necessitate the inspector revisiting the facility. Do **not** refer exporters to NCIE to check status of approval packages. Questions should come through the area office. When necessary, conference calls can be arranged among area offices, the IEC, NCIE, and, if necessary, the facility to clarify issues.
2. NCIE processes the checklist and provides final approval of the facility to export to the EU.

D. Communicating with the facility

The area office is the point of contact for the facility with APHIS. Area offices should advise applicants that their point of contact for information and questions about their approval is the area office. The area office should not direct applicants to NCIE or the IEC. The AVIC must attempt to answer all the facility's questions and concerns before seeking assistance from the IEC or NCIE.

XIII. EXPORT CERTIFICATION OF ANIMAL BY-PRODUCTS NOT FOR HUMAN CONSUMPTION TO THE EU

A. EU Requirements

1. **The exporter is always responsible for confirming that the proper certificate is properly completed and endorsed before shipment. The EU will not accept certificates endorsed after the product has been shipped.** Therefore, the area office should advise the exporters during the approval process that they must not ship prior to receiving any required export certificate. Moreover, because some countries within the EU may have separate, more restrictive lists, the area office should advise exporters to have their importers confirm that the shipment will be allowed entry on the issued certificate before shipment.
2. The EU requires export certificates to meet the following requirements:
 - Certificates must be bilingual in at least English and the official language of the country where the port of entry into the EU is located.
 - The original certificate must accompany the shipment.
 - The color of the signature on the certificate must be different than that of the printing. The same rule applies to stamps other than those embossed.
 - If the certificate is only two pages long, then the certificate must be printed one page front and back. While this is an EU requirement, APHIS believes certificates will be accepted that do not meet this requirement. Exporters must be informed of the requirement, but area offices should not refuse to sign certificates not completed as described in this bullet.
 - If a certificate is more than one sheet (more than two printed pages):
 - The signature appears on each page; **and**
 - The pages must be numbered at the bottom of each page as "(page number) of (total number of pages)"; **and**
 - The certificate number must be at the top of each page.
3. **Some EU countries require additional SRM certification statements to be included on certificates for animal by-products.** The exporter must confirm before requesting endorsement if these additional statements are needed on the export certificate. In cases where the exporter requires these statements, this information must be included on the same certificate (additional page if needed).

B. EU-required Zoosanitary Certificates

1. Regulation (EC) 1774/2002 and its related amendments establish harmonized import certificates for the majority of products covered by Regulation (EC) 1774/2002. Harmonized import certificates are those certificates where the EU has published a standard certificate to be used to import a commodity into a member country from outside the EU.
2. Regulation (EC) 1774/2002 does cover the import of some materials into the EU where no harmonized certificate has been published. In these cases, each EU member country may establish its own requirements for an import certificate. The exporter must have its importer contact the Ministry of Animal Health in the importing country to determine the certification requirements before shipment.

C. IREGS

1. The IREGs list certificates published in Regulation (EC) 1774/2002 separately from other information and harmonized EU certificates. The Regulation (EC) 1774/2002 certificates are located under the heading "Regulation (EC) 1774/2002 Certificates." Certificates and information for commodities not covered by Regulation (EC) 1774/2002 are located above this heading.
2. English versions of most published harmonized export certificates for animal by-products are available on the IREGS on the APHIS Web site.

D. Letterhead Certificates

No VS Form 16–4 may be issued when an EU letterhead certificate is issued. When a letterhead certificate must be bilingual and a bilingual version is not available on the IREGS, it is the responsibility of the exporter to create the document. Certificates must be prepared with the English portion and the other language side by side. This must be done either sentence by sentence or paragraph by paragraph.

IVX. ENDORSING THE CERTIFICATES

- A. Regulation (EC) 1774/2002 certificates may only be endorsed by officials who have received training on Regulation (EC) 1774/2002. If an official may need to endorse one of these certificates and has not yet received this training, the official must contact his or her supervisor or the IEC for assistance in obtaining the required training.

When area office personnel have questions regarding whether to endorse a certificate, they should direct their questions to their IEC, or up their chain of command if the IEC is unavailable.

- B. Area offices must ensure that facilities have been granted final approval by NCIE and are included in the list of facilities (available on the IDEA System) as being approved to export the commodity to the EU under Regulation (EC) 1774/2002.

The IDEA System specifies if the facility is approved under Regulation (EC) 1774/2002 and for what activities or commodities the facility is approved. A facility may be approved under Regulation (EC) 1774/2002 only to supply another facility in the United States material for further processing before export to the EU; while other facilities may be approved to export certain commodities directly to the EU.

From the IDEA home page (<http://inside.aphis.usda.gov/property/apps/idea.html>), the area office should select "Approved Animal Product Export Facilities" (<http://inside.aphis.usda.gov/authority/ncie/query-rpfdbs.html>). Next, the area office should select "Approved Export Facilities under EU Regulation 1774/2002" in the search criteria.

Approval in the IDEA System does not necessarily mean that all statements on an export certificate are true. The area office must take care to confirm that all statements on export certificates are true.

Because some countries are continuing to accept exports under the "old system," the IDEA System will retain that data until it is no longer relevant. This list may be searched by selecting "Approved Export Facilities under EU Directive 90/667/EEC."

Note: The information contained in both the above referenced areas of the APHIS Intranet is proprietary. Area offices should not give out this information available on the Intranet, except to verify certain products and or facilities are approved.

- C. Area offices should not assume that just because a facility has received approval under Regulation (EC) 1774/2002 and an export certificate for a given commodity is on the IREGS, that the certificate can be endorsed. In addition, Regulation (EC) 1774/2002 approval does not necessarily mean that the SRM declaration is accurate. Some countries, e.g. France, have a broader definition of SRMs. Endorsers must verify the certifications on the document are factual before endorsing the certificate.
- D. While VS does not verify the translation (we are endorsing the English portion as accurate) of a bilingual certificate, the area office must take care to ensure there is a reasonable likelihood that both languages say the same thing (each should be approximately the same length).
- E. The area office should check that the facility has a number. See section XV, "Facility Numbers."
- F. APHIS may only endorse one certificate for any exported material.

XV. FACILITY NUMBERS

NCIE issues facility numbers. VS may not endorse any export certificate for materials covered by Regulation (EC) 1774/2002 (materials produced in facilities described in section V above)—**unless** the facility number listed on the certificate is exactly the same as a number listed in the IDEA System, and the IDEA System indicates that the facility is approved under Regulation (EC) 1774/2002 to export the pertinent commodity to the EU.

In most cases, a facility will be assigned only one number, even if it holds several APHIS export approvals. The designation of a facility with an approval number does not signify approval under Regulation (EC) 1774/2002. An "APHIS export products approval number" only signifies that APHIS has approved the facility at some point in the past under some criteria.

XVI. FACILITY NAME OR ADDRESS CHANGES

Facilities must notify the AVIC directly of changes to names or mailing addresses. The AVIC should then send this notification to NCIE, Attention: Products Export Team, fax 301-734-0571. Until the change is noted in the IDEA System, export certificates must not reflect the change, as they must only refer to the facility as it is identified in the IDEA System.

"Mailing address" refers to a change in the street address for the same physical building. If a facility's physical address changes, the new facility will need to be inspected.

XVII. ANNUAL INSPECTION

For a facility to retain its approval, it must be inspected and reapproved at least once every 12 months. AVICs should contact facilities at least 2 months before the anniversary of the facility's last inspection and have the facility submit those documents that must be submitted annually (specified in the pre-inspection package).

After review of these documents, the area office must schedule an annual inspection of the facility. AVICs must advise facilities that they must complete the reinspection procedure before the annual anniversary of their last inspection in order to continue to export to the EU or to supply facilities who export to the EU. If a facility opts to not have an annual inspection, the AVIC must notify the facility that its approval will expire and must notify NCIE that the facility does not wish to continue being approved under Regulation (EC) 1774/2002.

If a facility has multiple approvals (e.g., approved as both a pet food facility and a digest/flavoring innard production facility), the area office must give the facility the option of receiving all necessary inspections during the same appointment. For example, if the facility was inspected for pet food facility approval on August 5, 2004, and digest/flavoring innard production facility approval on December 10, 2004, the area office could conduct the annual reinspection for both criteria before August 5, 2005. This would prevent the facility from having to be inspected twice in one year (unless questions were to arise).

The "Last Validated Inspection Date" for each facility is available on the IDEA System.

The AVIC is responsible for ensuring that all facilities are reinspected **at least every 365 days**, and that the required documents, along with a recommendation for reapproval or removal from the list of approved facilities, are forwarded to NCIE. Once NCIE validates that the facility still meets the requirements, the IDEA System is updated to indicate the most recent validated inspection date.

The reapproval process is the same as the initial approval. The AVIC should ensure that only the current version of the pre-inspection package is used.

If a facility declines to go through the reapproval process, the AVIC should forward an e-mail to Export Products indicating that the facility should be removed from the list of facilities approved under Regulation (EC) 1774/2002 and referencing the specific communication from the facility.

Area offices may not endorse export certificates for facilities if the IDEA System indicates that the last validated approval date was over a month ago, unless specific permission is given by NCIE.

John R. Clifford
Deputy Administrator
Veterinary Services

APHIS:VS:TWBurlison:DARoe:ext8905:0409-BLKPTS

APPENDIX ONE SEPARATION PROTOCOLS

The following information, excerpted from "Small Entities Compliance Guide for Renderers," FDA Guidance for Industry 67, Center for Veterinary Medicine, Food and Drug Administration, U.S. Department of Health and Human Services, February 1998, pages 7-11, describes the acceptable methods to be used by facilities to separate prohibited Category 1 and Category 2 materials from permitted materials.

HOW CAN I PROVIDE FOR MEASURES TO AVOID COMMINGLING OR CROSS-CONTAMINATION?

1. Separation

- You could have separate equipment or facilities for the manufacture, processing, blending, or storage of prohibited and nonprohibited materials. This could be entirely separate buildings, rooms, or other locations, or separate storage containers for incoming material and finished product, and separate manufacturing lines.
- Separate equipment for prohibited material should be clearly identified to help ensure that prohibited material is not mistakenly added to product intended to contain nonprohibited material only.

OR

2. Clean-out

- Clean-out could be physical cleaning, flushing, sequencing, or other means, either alone or in combination with separation measures that are adequate to prevent carryover of prohibited material into nonprohibited material. Clean-out procedures should be used on all equipment and conveyances that handle both prohibited and nonprohibited material.
- Documentation for clean-out should include a description of how clean-out is implemented – who is responsible; how clean-out is monitored and verified; how volume of clean-out flush material was determined; and a description of how clean-out flush material is handled.

OR

3. Combination of separation and clean-out

- An example would be use of some separate and some common equipment (clean-out would be required for the latter).

You need written procedures, whether you use separation, clean-out, or a combination:

- Written procedures should include the procedures followed from the time of receipt of incoming material until the time of shipment of finished products. They should reflect what actually happens in your operation.
- Written procedures should have enough detail to provide a clear understanding of your actual procedures. An investigator should be able to easily identify operations that are described in the written procedures.

WHAT ARE SOME EXAMPLES OF MEASURES THAT I COULD FOLLOW TO PREVENT COMMINGLING AND CROSS CONTAMINATION?

1. PROCESSING OPTION ONE

This example is a single plant with two or more totally segregated processing lines. This includes all process functions from raw material receiving through and including finished product load-out.

Suggested Procedures for Processing Option One

No clean-out procedures are necessary for this processing situation, because the lines are completely separate. This type of plant should have the ability to process prohibited and non-prohibited products from the same plant so long as procedures are in place to assure total segregation. These procedures should be part of the plant's written procedures specifying measures the firm is taking to prevent commingling and cross contamination and should be available for inspection and FDA review for compliance purposes.

2. PROCESSING OPTION TWO

This example is a single plant which has two or more segregated raw material receiving, grinding, cooking, and pressing lines but shares finished product conveying, grinding, and load-out systems.

Suggested Procedures for Processing Option Two

The suggested procedures to prevent commingling and cross contamination for this type of plant deal specifically with the meal grinding (and screening), storage, and load-out systems. It is assumed that this type of plant would have separate storage facilities for prohibited versus non-prohibited product. It may have separate or common load-out facilities.

STEP #1 - The first step in the clean-out and flushing procedure should be to empty all transport and processing equipment from the first point of commonality of products to the final load-out device.

STEP #2 - The system should then be flushed with a sufficient volume of non-prohibited product to accomplish one complete change of operating volume of the entire system (exclusive of separate meal storage facilities). The flush material should be considered prohibited product and treated as such.

STEP #3 - Once the system has been flushed, all subsequent material processed would be non-prohibited material. Specific operating procedures should be part of the plant's written procedures specifying the procedures to prevent commingling and cross contamination and available for inspection and FDA review for compliance purposes.

3. PROCESSING OPTION THREE

This example is a single plant with separate raw material receiving and grinding, common cooking and pressing, and common or separate finished product handling.

Suggested Procedures for Processing Option Three

The procedures to prevent commingling and cross contamination for this type of plant deal specifically with the cooking and pressing systems. The meal grinding, storage, and load-out systems should be cleaned and flushed according to the guidance in processing option two above. It is also assumed that this type of plant would have separate storage facilities for prohibited versus non-prohibited finished meal. It may have separate or common load-out facilities.

STEP # 1- The first step should be to empty all transport and process equipment (including the cooker) from the first point of commonality of raw material to the meal grinding system.

STEP # 2- The system should then be cleaned and/or flushed with sufficient non-prohibited raw material to accomplish the following changes of the operating volume of the cooker:

- In the case of a continuous cooker with a bottom discharge (to provide positive cooker clean-out), raw material equal to at least one half the operating volume of the cooker;
- In the case of a continuous cooker without a bottom discharge, raw material equal to at least the operating volume of the cooker; or
- In the case of a batch cooker system, raw material equal to at least one half the operating volume of the cooker for each batch cooker.

In general, the volume of material required to flush the cooking system should provide an adequate flush of the meal grinding, storage, and load-out system, as well. The flush material should be considered prohibited product and treated as such. All subsequent material processed should be considered non-prohibited product.

Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross contamination, and should be available for inspection and FDA review for compliance purposes.

4. PROCESSING OPTION FOUR

This example is for a single plant with one processing line handling both prohibited and non-prohibited material. This includes all process functions from raw material receiving through and including product load-out.

Suggested Procedures for Processing Option Four

The procedures to prevent commingling and cross contamination for this type of plant deal with the complete plant process. It is assumed that this type of plant would have adequate storage facilities to separate prohibited from non-prohibited finished product. It may have separate or common load-out facilities.

The procedures should include measures to empty and clean and/or flush all transport and process equipment including the raw material receiving hoppers, conveyors, grinders, and cooker from the first point of commonality of raw material through the load-out system. As a guideline, the volume of flushing material should be equal to the operating volume of the process and transport equipment, including the cookers.

The flush material should be considered prohibited product and treated as such. All subsequent material processed should be considered non-prohibited product. Specific operating procedures should be documented and verified, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross contamination and should be available for inspection and FDA review for compliance purposes.

Due to the degree of variability among rendering systems, a Hazard Analysis and Critical Control Points (HACCP)-based approach of process controls would be helpful in implementing any of the above procedures. This will enable differences to be addressed on a site-specific basis. Renderers could follow the above clean-out procedures by determining their plant's individual characteristics and apply appropriate time and volume requirements for flushing material to accomplish the intent of the procedures. Individual clean-out procedure, including time and volume calculations, should be part of the plant's written procedures specifying the procedures utilized to prevent commingling and cross-contamination and should be available for inspection and FDA review for compliance purposes.